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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/004,946	03/23/1998	5554121	1001.5094105	9950

and 09/143,503

EXAMINER

23446 7590 01/30/2009

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500 WEST MADISON STREET
SUITE 3400
CHICAGO, IL 60661

ART UNIT	PAPER NUMBER

DATE MAILED: 01/30/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	09/143,503	AINSWORTH ET AL.	
	Examiner	**Art Unit**	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Patentee's submission filed on 08/27/2008 has been entered.

Formal Matters/Response to Amendment

The Examiner acknowledges the multiple exhibits (58) filed 08/27/2008 and supporting **declarations** of Lawrence Wasicek and Robert Ainsworth under 37 CFR 1.131. to overcome the Beisel, WO94/01160 reference.

The Examiner also acknowledges the **petition decision** filed 01/19/2009 which was granted and the reissue application is hereby accorded Rule 1.47(a) status.

Pantentee must provide the assignee's written consent to the reissue in accordance with 37 CFR 1.172(a). There is **no correct combined assignee consent and 37 CFR 3.73(b) statement** filed in the case. The combined submission listed the assignment as being recorded under Reel 1266 / Frame 620 which does not correspond with the office's records; the correct assignment appears to be Reel 7266 / Frame 619. A new consent and 37 CFR 3.73(b) statement to reflect the current assignee is required. Appropriate correction required.

Currently claims 1-64 are pending for examination in this application.

Claim Objections

Claim 15 is objected to because of the following informalities: **Regarding claim 15, the following minor error** is present within the claim body, "...an elongation greater than about 60 % and a tensile...". Appropriate correction is required.

Defective Reissue Oath/Declaration, Rejection under 35 U.S.C 251

The reissue oath/declaration filed 12/17/2008 failed to properly identify at least one 35 U.S.C.251 error. **It is not sufficient** for an oath/declaration to merely state "Claim 1 of U.S. Patent No. 5,554,121, as originally issued, requires as one element a dilatation balloon." Patentee seeks to obtain claims having a scope broader than the scope of the claims in the issued patent. Rather, the oath/declaration must specifically identify an error. Any error in the claims must be identified by reference to the specific claim(s) and the specific claim language wherein lies the error. (MPEP 1414 II. (C)). The differences between the newly added claims 18-64 and the original claims 1-17 should be pointed out. See In re Constant, 827 F.2d 728, 729, 3 USPQ2d 1479 (Fed. Cir.), cert. denied, 484 U.S. 894 (1987). This generalization of term of the "balloon" is insufficient to identify a 251 error. The specific claim language is required.

The **error statement** in the reissue oath or declaration filed 12/17/2008 with the presentation of added claims 18-64 is not considered a sufficient "error"

statement since applicant has not pointed out what the other claims 1-17 lacked that the newly added claims 18-64 have, or vice versa.

Claims 1-64 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the oath/declaration is set forth in the discussion above in this Office action.

Recapture, Rejection under 35 U.S.C 251

Claims 18-64 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

As previously detailed in prior office actions by the last Examiner, the three step test for recapture is used for as described in MPEP 1412.02. In Clement, 131 F.3d at 1468-70, 45 USPQ2d at 1164-65, the Court of Appeals forthe Federal Circuit set forth a three step test for recapture analysis. In **> North American Container, 415 F.3d at 1349, 75 USPQ2d at 1556, the court restated this test as follows:

We apply the recapture rule as a three-step process:

(1) first, we determine whether, and in what respect, the reissue claims are broader in scope than the original patent claims;

(2) next, we determine whether the broader aspects of the reissue claims relate to subject matter surrendered in the original prosecution; and

(3) finally, we determine whether the reissue claims were materially narrowed in other respects, so that the claims may not have been enlarged, and hence avoid the recapture rule.

See North American Container, the court cited Pannu, 258 F.3d at 1371, 59 USPQ2d at 1600; Hester, 142 F.3d at 1482-83, 46 USPQ2d at 1649-50; and Clement, 131 F.3d at 1468, 45 USPQ2d at 1164-65 as cases that lead to, and explain the language in, the North American Container recapture test.

Following this rationale, the prior history of the '121 patent, specifically directed to the amendment filed 12/01/1995, pages 3-5, in which Patentee specifically argues:

"...For example, enclosed are copies of the Table of Contents and page A-31 of International Plastics Selector-Plastics Digest which indicates that while PVC may have a tensile modulus of more than 300,000 psi, it does not have a tensile strength above 10,000 psi even at high tensile modulus. It would thus appear that the Hamlin reference would not suggest, as the

Examiner contends, to form the proximal shaft of the catheter from a material such as PEEK having al .of the properties set...."

Regarding step two of the recapture test, the specific materials properties (tensile modulus of more than 300,000 psi and a tensile strength above 10,000 psi) were argued as the defining feature over the prior art, therefore there is an improper recapture since the new claims 18, 53 and 57 do not recite these features. Additionally, **regarding step three of the recapture test**, the claims 18, 53 and 57 have been broadened by omission of these specific properties as well as removal of the balloon element, with no specific narrowing in any other respects, again resulting an improper recapture.

Claim Rejections - 35 USC § 102

Claims 57-64 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beisel, WO 94/01160 with reference Muni et al., U.S. 5,316,706 and to Bennett et al.,U.S. 5,221,728. Beisel discloses an epidural catheter which may be inserted intravascularly and in addition the catheter's objective is to lower the incidence of blood vessel puncture, for example. See page 5, lines 8-15. Accordingly, Beisel discloses the claimed preamble "intraluminal catheter" since the epidural space in an intraluminal space as claimed, and Beisel also discloses the intended use of the device, for advancement into the patient's vasculature. Patentee's arguments as to the preamble are noted, however, it is well settled that the intended use of a device is not accorded much patentable weight, particularly when the body of the

claim, as here, does not refer back to the preamble or otherwise breathe "life and vitality" into the preamble.

Regarding the body of the claim, Beisel discloses the shaft portions comprising PEEK and the claimed "tensile modulus greater than 400,000 psi." See page 7, third column, last line, the data for PEEK, 0..51 x 106 psi or 510,000 psi. Patentee also claims an elongation at break of greater than 50%, greater than 60% (claim 59) while Beisel is silent as to the elongation at break data, which is not uncommon in the catheter art.

The Examiner takes the position that the Beisel catheter inherently possesses this characteristic as evidenced by Bennet. See, for example, Bennett, column 5, lines 45-60. A PEEK polymer was extruded and tested for modulus of elasticity, tensile strength and elongation at break. Note that the "modulus of elasticity" (also known as "flexural modulus", "tensile modulus," or more accurately, "tensile modulus of elasticity") cited by Bennett (2.4 GPa) is similar to that disclosed by Beisel, (3.5 GPa). The tensile strength of Bennett (107 MPa) is similar in range to that disclosed by Beisel (93.8 MPa). However, Beisel does not disclose an elongation at break. Bennett shows that a PEEK polymer with the same other characteristics of Beisel has an elongation at break of 156%. Accordingly, the examiner takes the position that Beisel inherently discloses the modest elongation at break claimed by Patentee, being greater than 50% (claim 57) and 60% (claim 37).

Muni is again relied on to exemplify that the concept of extruding PEEK (column 4, line 33) angioplastic catheters to improve stiffness and pushability

was well known when the Beisel invention was conceived in the early 90's. Beisel discloses the catheter may be extruded on page 10, lines 12, and Muni is relied on to show what this process involves.

Regarding the elongation at break, Patentee argues (page 5, lines 9+ of the response filed February 5, 2007) that tensile modulus, strength and elongation are properties which are inter-related and vary with the material processing conditions, particularly with regard to crystallinity and the manner in which the polymer is processed. While some of these issues are not disputed, the examiner still does not agree the claims are allowable for the following reasons.

Firstly, elongation at break is hardly ever discussed in the catheter art, accordingly, the absence of a disclosure of elongation at break in the prior art cannot generate the basis of a novel invention. Secondly, an elongation at break greater than 50%, or 60%, is a modest range. There is nothing unusual about this embodiment which one would not expect to find in the prior art. Thirdly, the Bennett '728 patent is provided to show an elongation at break of 156% for commercial PEEK (VICTREX PEEK 450 G manufactured by ICI). See column 5, lines 44-60. As stated in Patentee's '121 patent, the particularly preferred resin for the outer tubular member is formed of PEEK (grade 381) from VICTREX. This information, in addition to the information provided by Beisel, page 7, Table 1, shows how similar these polymers are in terms of mechanical properties. Fourthly, although Patentee argues that the manner of polymer processing is critical to the final properties of the polymer (and there is no disagreement here),

the examiner points out that Patentee has not disclosed any extruding technique which would yield a catheter having unexpected properties, nor are these embodiments claimed in a product by process type claim, even if the particular polymer processing had been disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-22, 26, 27, 31-48, 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beisel, WO 94/01160 in view of Goltzer, US 4,973,305 with reference to Muni et al., U.S. 5,316,706 and Bennett et al., U.S. 5,221,728. As stated in the previous office action, Beisel discloses an epidural catheter that is inserted intravascularly. Accordingly, Beisel discloses an intraluminal catheter for percutaneous insertion as claimed in the preamble. See Beisel, page 2, lines 13-23. Regarding the body of the claim, Beisel discloses that the stiff inner tube 12 may comprise PEEK (page 6, line 21). Distal portion 10 comprises the soft

outer tube and anticipates the claimed more flexible distal shaft portion. Regarding the tensile strength, note page 7 and the tensile strengths listed therein. For PEEK, the tensile strength given is 13.6 x 10^3 psi, or 136,000 psi. Regarding the extruded limitation of the proximal shaft portion of claim 18, and noting the limitations of claims 51 and 52, see Beisel, page 10, line 12, which states that the epidural catheter can be constructed by known manufacturing processes "such as extrusion, drawing and the like." The examiner takes the position that this disclosure anticipates the claim portion directed to the extruded proximal shaft.

In the alternative, Muni is cited to exemplify that the concept of extruding PEEK (column 4, line 33) angioplastic catheters to improve stiffness and pushability was well known when the Beisel invention was conceived in the early 90's. Accordingly, it would be obvious to one of ordinary skill in the art to extrude inner PEEK tube 12 of Beisel according to Muni so that the catheter exhibits improved pushability.

Patentee has amended claim 18 to require a dilatation balloon on the distal shaft portion. The examiner takes the position that Beisel discloses all of Patentee's claim 18 embodiments with the exception of the balloon. Goltzer '305 discloses an epidural catheter with a distal balloon retention means 12. See especially figure 2 on sheet 2. The purpose of the balloon is to anchor an epidural catheter securely in place for extended lengths of time. See column 2, lines 10-28. Beisel does not disclose a balloon anchoring device, however, it would be obvious to one of ordinary skill in the art to apply a Goltzer balloon to

the Beisel shaft for the purpose of anchoring the Beisel shaft if the epidural catheter were desired for long term placement.

Regarding claim 19, Beisel discloses the PEEK on page 7.

Regarding claims 31-34, 53+, note again page 7 and the tensile/flexural modulus disclosed therein. The third column discloses a PEEK tensile modulus of 0.51 x 10^6 psi, or 510,000 psi. Regarding claim 35, note that the PAEK polymer has a tensile strength of 17.6 x 10^3 psi. Regarding claims 43-48 reciting the intended use, note that the Beisel catheter is inserted intravascularly, and there is discussion of preventing "blood vessel puncture" on page 5, line 13.

Regarding claims 20, 21, 37-42, 55-56, reciting the elongation at break, again, the examiner admits that Beisel is silent as to the elongation at break data, which is not uncommon in the catheter art. However, the examiner takes the position that the Beisel catheter inherently possesses this characteristic as evidenced by Bennet. See, for example, Bennett, column 5, lines 45-60. A PEEK polymer was extruded and tested for modulus of elasticity, tensile strength and elongation at break. Note that the "modulus of elasticity" (also known as "flexural modulus", "tensile modulus," or more accurately, "tensile modulus of elasticity") cited by Bennett (2.4 GPa) is similar.to that disclosed by Beisel, (3.5 GPa). The tensile strength of Bennett (107 MPa) is similar in range to that disclosed by Beisel (93.8 MPa). However, Beisel does not disclose an elongation at break. Bennett shows that a PEEK polymer with the same other characteristics of Beisel has an elongation at break of 156%. Accordingly, the examiner takes the position

that Beisel inherently discloses the modest elongation at break claimed by Patentee, being greater than 50% (claims 20, 57) and 60% (claim 37).

Claims 18, 24, 25 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muni et al., U.S.5,316,706 with reference to Beisel, WO 94/01160. Muni discloses the balloon.angioplasty catheter (column 3, line 58) but fails to disclose the catheter properties. Beisel is cited to exemplify that the ranges cited by Patentee are known in the art for PEEK intravascular catheters. Accordingly, the examiner takes the position that Muni inherently discloses the claimed range. In the alternative, it would be obvious to one of ordinary skill in the art to make the Muni catheter with the tensile strength, tensile modulus as shown by Beisel so that the catheter would be able to traverse blood vessels without puncturing the walls of the blood vessels. Regarding claim 25, the feature recited is inherent for the operability of a balloon catheter.

Claim Rejections - 35 USC § 103

Claims 28-30, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beisel, WO 94/01160 with reference to Muni et al., U.S. 5,316,706. Regarding claims 28-30, Patentee merely reverses the layering of the Beisel catheter, requiring that the proximal portion of the outer tubular member be made of the extruded material having the increased tensile strength. However, it is well established that the rearrangement of parts of prima facie obvious in the lack of a showing of criticality. See MPEP 2144.04 IV.C., entitled "Rearrangement of Parts," and note that the examiner may use legal precedent

to provide the rationale supporting obviousness in this situation. In view that the examiner can find no evidence of unexpected results in the specification that would support patentability of this simple reversal, these claims must be rejected, Regarding claims 49 and 50,-citing the length of the catheter, the Beisel length is recited on page 5, lines 29-35 as being a preferred length of 91.4 cm. Clearly, the Beisel catheter is not intended to be limited to this exact length. Further, it is well established that catheter lengths vary dependent on patient need, and are selected according to the size of the patient. An infant would have a smaller sized catheter than a large adult.

Claims 23, 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al., '706 in view of Beisel, WO '160 as applied to claims 18, 24 and 25 above, and further in view of Cornelius et al., US 5,423,754. Muni discloses a balloon angioplasty catheter but fails to detail the features commonly applied to these catheters. The Muni patent is primarily dedicated to the type of polymers and the method of making the catheter shaft. Patentee's claims 23, 1-17 point out the particular catheter structure desired. Cornelius exemplifies that the structure of inner and outer catheters, and the dilation balloon, the guide wire lumen, and with the various hard and soft areas are well known features in a balloon angioplasty catheter. It would be obvious to one of ordinary skill in the art to provide the Muni angioplasty catheter with angioplasty catheter features as shown by Cornelius, in order to make the Muni catheter operable for its intended purpose. An angioplasty catheter will not be operable,

or will be barely operable (an imagined embodiment without a guide wire lumen), without the Cornelius features.

Response to Arguments

The declarations of Lawrence Wasicek and Robert Ainsworth filed on 08/27/2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Beisel, WO'160 reference. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Beisel, WO '160 reference of January 20, 1994. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Patentee is required to show conception of the currently claimed subject matter of all claims that are being overcome by the CFR 1.131 affidavit. The examiner asserts the documentation shown in exhibits 1-3 fails to show conception of the claimed subject matter of claims 18-64. **Regarding exhibit one**, the document provided merely cites an engineered plastic (e.g. PEEK, PAK, etc) with a balloon section having higher strength and pressure of 7300 psi, and a shaft of higher pressure and strength. **Regarding exhibit two**, the document provided cites no further claim scope limitations. **Regarding exhibit three**, the document provided discloses a materials test report that discloses a specific thermoplastic, PEEK 381G, and test run data for several tests of stress, strain, and load at max load and at break. The data

ranges provided in exhibit three are inconsistent with the scope of the current claims 18-64.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 1/15/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/004,946 and reissue 09/143503*.

PATENT NO. *5,554,121*.

ART UNIT *3763*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).